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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,380	12/27/2001	James Hong	ACS 57402	7795

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EXAMINER	
ORTIZ, ANGELA Y	
ART UNIT	PAPER NUMBER
1732	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/033,380

Applicant(s)

HONG ET AL.

Examiner

Angela Ortiz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☒ Claim(s) 19-20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4.5.10</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 1- 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over PCT WO 01/21101 A1 in view of Chouinard, USP 6,156,064 (both references already of record).

The cited primary reference substantially teaches the basic claimed method of making a stent comprising the steps of providing a stent on a mandrel, providing a cover and supplying resin around the stent within the cover to form a stent-assembly. The stent further comprises a plurality of unitary circular members, which are readable on the claimed stent rings. The stent is also formed of an expandable material, and in a further embodiment, the stent can be expanded prior to implantations, see page 17, lines 20-25. The rings are further aligned along a common axis. A cover may be provided to form a cavity surrounding the stent while on the mandrel. The molding material may be supplied to the cavity to form connecting members using conventional molding techniques. See pages 6-8 and page 11, line 28 to page 13, line 15.

The cited primary reference does not teach the claimed step of dip coating a membrane over the stent.

The added secondary reference teaches as conventional the feature of forming an encapsulated stent by providing the stent on a mandrel and dip coating a material around the stent such that the material encapsulates the stent. The reference further teaches that the stent comprises a stent-graft-membrane are wound and are constrainable to a first diameter and self-expandable to an increased diameter. The stent further comprises a tubular mesh of wound filaments, that is provided on a mandrel and a membrane material is applied to the stent to form a membrane surface.

The membrane is intended to limit permeability of the stent and comprises a polymer solution that can be dip-coated onto the stent. See col. 9 lines 7-65.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a dip-coating method for applying the membrane over the stent as shown in the added reference, when performing the process set forth in the primary reference, to encapsulate the stent ring-assembly and to limit permeability of the stent.

With respect to claim 2, note that USP 6,156,064 (secondary reference) teaches use of a TFE release coat on the mandrel, see col. 10, lines 9-11. It would have been obvious to use a mandrel of the same material for achieving equivalent release properties.

With respect to claims 3, 8, and 9, note that USP 6,156,064 (secondary reference) teaches that the membrane may be provided on the inside or outside of the stent, see col. 9, lines 57-67. When the membrane is applied to the interior surface, the mandrel is first dip-coated and then the rings may be provided. See col. 11, lines 1-30.

With respect to claims 4, 5, 6, and 11, note that PCT WO 01/21101 A1 (primary reference) teaches that the rings (2, 18, 20, 26) and connecting members are flexible, made from a metal or equivalent material and have a conventional thickness range. See page 6, lines 30-35; page 7, lines 1-15; page 9, lines 1-6; page 11, lines 7-20.

With respect to claims 7 and 10, see USP 6,156,064 (secondary reference) at example 1.

With respect to claims 12-15, note that that PCT WO 01/21101 A1 (primary reference) teaches the use of a drug delivery system at page 17, lines 30-35; and shape modifications at page 18, lines 1-5.

With respect to claims 16-18, note that the secondary reference sets forth multi-layered stents; see col. 11, lines 30-67.

Allowable Subject Matter

Claims 19-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela Ortiz whose telephone number is 571-272-1206. The examiner can normally be reached on Monday-Thursday 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Colaianni can be reached on 571-272-1196. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Angela Ortiz
Primary Examiner
Art Unit 1732

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